

Amended Claims

1. **(currently amended)** A self-emulsifying drug delivery system, ~~wherein: comprising~~
the system comprises a mixture of an extremely water-insoluble, lipophilic active agent;
polyvinylpyrrolidone; a fatty acid; and a surfactant; ~~and , wherein~~
the polyvinylpyrrolidone has a molecular weight of **from** about 2,500 to about 20,000.

2. **(currently amended)** The self-emulsifying drug delivery system of claim 1, wherein:
the weight ratio of **the** ~~[[said]]~~ fatty acid to **the** ~~[[said]]~~ polyvinylpyrrolidone is **from**
about 2:1 to about 1:3, and
the weight ratio of **the** ~~[[said]]~~ surfactant to **the** ~~[[said]]~~ polyvinylpyrrolidone is **from**
about 10:1 to about 1:1.

3. **(currently amended)** The self-emulsifying drug delivery system of claim 1, wherein:
the extremely water-insoluble, lipophilic active agent has a log P equal **to** or greater than
2, and
the extremely water-insoluble, lipophilic active agent has a solubility of less than 100
micrograms per milliliter of water.

Claims 4-5 (canceled).

6. **(currently amended)** The self-emulsifying drug delivery system of claim 1, wherein
the amount of polyvinylpyrrolidone is **from** ~~[[about]]~~ 5% to about 40%, by weight of the self-
emulsifying drug delivery system.

7. **(currently amended)** The self-emulsifying drug delivery system of claim 1, wherein
the amount of fatty acid is **from** about 5% to about 35%, by weight of the self-emulsifying drug
delivery system.

8. **(currently amended)** The self-emulsifying drug delivery system of claim 1, wherein the amount of fatty acid is **from** about 5% to about 15%, by weight of the self-emulsifying drug delivery system.

9. **(original)** The self-emulsifying drug delivery system of claim 1, wherein the fatty acid is a fatty acid containing from about 6 to about 18 carbons.

10. **(original)** The self-emulsifying drug delivery system of claim 9, wherein the fatty acid is selected from the group consisting of hexanoic acid, octanoic acid, nonanoic acid, decanoic acid, lauric acid, linoleic acid, oleic acid, palmitic acid, and mixtures thereof.

11. **(original)** The self-emulsifying drug delivery system of claim 1, wherein the surfactant is selected from the group consisting of polyoxylated castor oil, polyoxylated glycerides of fatty acids, polyoxyethylene sorbitan fatty acid esters, polyglycolized glycerides, and mixtures thereof.

12. **(original)** The self-emulsifying drug delivery system of claim 1, wherein the surfactant is selected from the group consisting of polyoxyl 35 castor oil and polysorbate 80.

13. **(currently amended)** The self-emulsifying drug delivery system of claim 1, wherein the amount of surfactant is **from** about 20% to about 70%, by weight of the self-emulsifying system.

14. **(currently amended)** The self-emulsifying drug delivery system of claim 13, wherein the amount of the surfactant is **from** about 30% to 50%, by weight of the self-emulsifying system.

15. **(original)** The self-emulsifying drug delivery system of claim 1, further comprising an antioxidant selected from the group consisting of ascorbic acid, ascorbyl palmitate,

butylhydroxyanisole, butylhydroxytoluene, propyl gallate, sodium ascorbate, tocopherol, and mixtures thereof.

16. **(original)** The self-emulsifying drug delivery system of claim 1, further comprising a pharmaceutically acceptable organic solvent.

17. **(original)** The self-emulsifying drug delivery system of claim 14, wherein the solvent is selected from the group consisting of ethanol, a polyethylene glycol, propylene glycol, and mixtures thereof.

18. **(currently amended)** The self-emulsifying drug delivery system formulation of claim 1, comprising:

from about 1 wt. % to about 4 wt. % the extremely water-insoluble, lipophilic ~~[[said]]~~ active agent;

from ~~[[about]]~~ 5 wt. % to about 40 wt. % the ~~[[said]]~~ polyvinylpyrrolidone;

from about 5 wt. % to about 35 wt. % the ~~[[said]]~~ fatty acid; and

from about 20 wt. % to about 70 wt. % the ~~[[said]]~~ surfactant.

19. **(currently amended)** The self-emulsifying drug delivery system formulation of claim 1, wherein the extremely water-insoluble, lipophilic active agent is a steroid, an anticancer agent, an antifungal agent, or antiinfective agent.

20. **(currently amended)** The self-emulsifying drug delivery system formulation of claim 1, wherein the extremely water-insoluble, lipophilic active agent is selected from the group consisting of progesterone, ketoconazole, itraconazole, metroxyprogesterone, and paclitaxel.

Claims 21-24 (canceled).

25. (currently amended) The self-emulsifying drug delivery system formulation of claim 1, wherein the self-emulsifying drug delivery system formulation is filled into a gelatin capsule.

26. (currently amended) The self-emulsifying drug delivery system formulation of claim 25, wherein the gelatin capsule is a hard-shelled gelatin capsule, a soft-shelled gelatin capsule, or a hydroxypropyl methylcellulose capsule.

27. (currently amended) The self-emulsifying drug delivery system formulation of claim 1, wherein the self-emulsifying drug delivery system formulation is for oral administration ~~administered orally, parenterally, rectally, or topically.~~

28. (withdrawn-currently amended) A method of treating and/or preventing a condition in need of a therapeutic regimen comprising a steroid, an antifungal agent, an antibacterial agent, or an anticancer agent, wherein the method comprises ~~comprising the step of~~ administering a self-emulsifying drug delivery system of claim 1 ~~comprising a mixture of a therapeutically effective amount of at least one extremely water-insoluble, lipophilic active agent; polyvinylpyrrolidone; a fatty acid; and a surfactant to an individual in need thereof, wherein the weight ratio of said fatty acid to said polyvinylpyrrolidone is about 2:1 to about 1:3.~~

29. (withdrawn-currently amended) The method of claim 28, wherein the weight ratio of the ~~the~~ [[said]] surfactant to the ~~the~~ [[said]] polyvinylpyrrolidone is about 10:1 to about 1:1.

30. (withdrawn-currently amended) The method of claim 28, wherein:
the extremely water-insoluble, lipophilic active agent has a log P of equal to or greater than 2, and
the extremely water-insoluble, lipophilic anticancer active agent has a solubility of less than 100 micrograms per milliliter of water.

31. **(withdrawn-currently amended)** The method of claim 28, wherein the extremely water-insoluble, lipophilic active agent is ~~an anticancer agent~~ selected from the group consisting of paclitaxel and ~~[[or]]~~ an indolinone compound.

32. **(withdrawn-currently amended)** The method of claim 28, wherein the self-emulsifying drug delivery system formulation is administered in combination with at least one additional active agent.

33. **(withdrawn-currently amended)** The method of claim 32, wherein the self-emulsifying drug delivery system formulation is administered in combination with an active agent selected from the group consisting of vascular endothelial growth factor, 5-fluorouracil, leucovorin, irinotecan HCl, epirubicin, taxotere, taxol, carboplatin, gemcitabine, cisplatin, oxaliplatin, 5-azacitidine, a signal transduction inhibitors, a cytostatic compound, and mixtures thereof.

34. **(withdrawn-currently amended)** The method of claim 28, wherein the extremely water-insoluble, lipophilic active agent is ~~a steroid, an antifungal agent, or antibacterial agent~~ selected from the group consisting of progesterone, ketoconazole, itrazone, and metoxyprogesterone.

35. **(withdrawn-currently amended)** Use of a self-emulsifying drug delivery system of claim 1 ~~composition comprising an extremely water-insoluble, lipophilic active agent, polyvinylpyrrolidone, a fatty acid, and a surfactant, wherein the weight ratio of said fatty acid to said polyvinylpyrrolidone is about 2:1 to about 1:3,~~ for the manufacture of a medicament, wherein the ~~for a condition in need of a therapeutic regimen comprising an extremely water-insoluble, lipophilic~~ active agent is selected from the group consisting of a steroid, an antifungal agent, an antibacterial agent, and an anticancer agent.

36. **(new)** The use claim 35, wherein the weight ratio of the fatty acid to the polyvinylpyrrolidone is from about 2:1 to about 1:3.

37. **(new)** The self-emulsifying drug delivery system of claim 1, wherein the self-emulsifying drug delivery system is for parenteral administration.

38. **(new)** The method of claim 28, wherein the weight ratio of the fatty acid to the polyvinylpyrrolidone is from about 2:1 to about 1:3.

39. **(new)** The method of claim 28, wherein the self-emulsifying drug delivery system is administered orally.

40. **(new)** The method of claim 28, wherein the self-emulsifying drug delivery system is administered parenterally.